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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,143	09/09/2003	Yoo-Hun Suh	P24188	1665

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 12/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/657,143	SUH ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) *2-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Response to Amendment

The amendment filed 8/31/2005 amended claim 1, cancelled claims 2-20 and added new claims 21-32, additionally the specification was to be amended as described on page 3 of the amendment. As detailed below the amendment to the specification is objected to as adding new matter, the new claims 21-32 are withdrawn from consideration due to original presentation, leaving amended claim 1 for consideration based on its merits.

The amendment filed 8/31/2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The applicant's amendment to the specification, on page 3, states:

"The present invention also provides a method for treating dementia in a patient, comprising administering a therapeutically effective amount of minocycline to a patient in need thereof to inhibit brain cell toxicity of C-terminal protein.

The present invention also provides a method for treating memory impairment in a patient, comprising administering a therapeutically effective amount of minocycline to a patient in need thereof to inhibit brain cell toxicity of C-terminal protein."

The applicant's state, on page 6, of the remarks:

"The specification has also been amended herein to explicitly include the language of the claims."

The examiner respectfully points out that the claims as originally filed on 09/09/2003 were drawn to pharmaceutical compositions and that the preliminary amendment to the claims filed 10/31/2003 included only claims drawn to pharmaceutical compositions. There were no method claims in either claim set.

There is no support for the methods detailed in the applicant's proposed amendment to the specification from the claims and thus is new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Election/Restrictions

Newly submitted claims 21-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 21-32 are drawn to a "...method of treating...", however the claims examined and addressed in the first office action were drawn to pharmaceutical compositions. If the applicants originally included the method claims in the claims examined in the first office action, the examiner would have required an election/restriction between the composition and method claims. To support this the examiner is including an example restriction requirement between Invention I drawn to pharmaceutical compositions comprising minocycline and Invention II drawn to methods of treating dementia in a patient by administration of pharmaceutical compositions comprising minocycline. Inventions I and

II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process of treating dementia can be accomplished by using various therapeutic agents, such as aspirin and other NSAIDS, acetyl cholinesterase inhibitors, selective serotonin reuptake inhibitors and other neurotransmitter affecting agents. Additionally minocycline is a known antibacterial agent and is effective in treating tetracycline-resistant infections.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21-32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

The 112-1 rejection over "...preventing..." is overcome by the amendment to claim 1, thus the 112-1 rejection is withdrawn.

Applicant's arguments filed 8/31/2005 over the 102(b) rejection of claim 1 have been fully considered but they are not persuasive. The applicant's assert that the preamble of the composition claims gives life, meaning, and vitality to the claims and should be considered as part of the claim. The examiner respectfully disagrees with the

applicant. The preamble of the present amended claim 1 is still an intended use and thus not afforded patentable weight. The amending of claim 1 necessitates a new 102(b) rejection. The new 102(b) rejection is detailed below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Rydel et al. (US Patent No. 5707821).

Rydel et al. teach, in col. 19 lines 10-65, that compounds capable of inhibiting PLA2 and neuronal degeneration in Alzheimer's disease models can be used to retard or reduce AD-type neuropathology in vivo, and thus can be formulated in a pharmaceutically acceptable carrier for parenteral, topical, and oral administration.

Rydel et al. teach, in Example 5 and Table 3, pretreatment of human cortical neurons with a series of PLA2 inhibitors (including minocycline) and subsequent exposure of the pretreated human cortical neurons to Aβ1-40 at concentrations of 90nM to 100μM in ddH2O (a pharmaceutically acceptable carrier), in order to determine the effects of the compounds on neuronal survival. Table 3 demonstrates that minocycline inhibits PLA2 and protects human neurons from toxicity due to exposure to pathogenic

Aβ peptide anticipating the "...pharmaceutical composition...which contains minocycline...." of claim 1.

The examiner respectfully points out the following: A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. v. Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

LMW